IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

DR. MARK BARRY,	:	
Plaintiff,	:	
	:	
v.	:	**Civ. No. 17-3003**
	:	
DEPUY SYNTHES PRODUCTS, INC., *et al.*,	:	
Defendants.	:	

Diamond, J. July 28, 2023

MEMORANDUM

Retired orthopedic surgeon Mark Barry alleges that medical device manufacturer DePuy induced surgeons to infringe his patents respecting surgical techniques and systems for correcting spinal deformities. (Am. Compl. (Doc. No. 20-2)); 35 U.S.C. § 271(b). Before trial, DePuy moved under Daubert to exclude the survey and expert testimony of Dr. David Neal. (Doc. No. 135); Daubert v. Merrell Dow Pharms., Inc., 509 U.S. 579, 589 (1993). I denied the Motion without prejudice, explicitly cautioning that this pretrial ruling was "necessarily tentative." (Doc. No. 185.) At trial, DePuy renewed its Daubert Motion, which I granted after hearing Neal's testimony and reviewing the Parties' additional briefing. (Doc. Nos. 235, 241, 252). I indicated that I would issue this Memorandum in which I would explain the bases of my decision more fully.

I. FACTUAL BACKGROUND

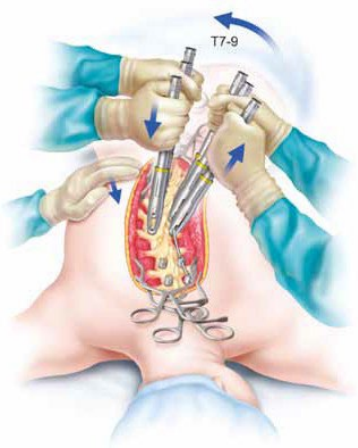
Because the record is voluminous and complex, I set forth only those facts necessary for resolution of DePuy's renewed Daubert Motion. (Doc. No. 235.)

A. Patents at Issue

Dr. Barry's three patents involve surgical techniques and systems for correcting conditions by which vertebrae (the series of bones making up the spine) twist out of alignment. (Trial Day 1 Tr. at 111:11-16.)

Each vertebra has two pedicles: short bone projections on opposite sides that join to form the hollow archway housing the spinal cord. Although spine surgeons have used "pedicle screws" (rod-housing screw systems inserted into vertebrae through the pedicles) as stabilizing forces in corrective procedures since the 1990s, only in the early 2000s did surgeons determine that they "could put tools on top of the pedicle screwhead" to manipulate, or "derotate," the underlying vertebrae directly. (Id. at 117:18-21, 119:21-23, 120:10-19.) Surgeons attached levers to these screwheads and, by applying force to individual levers, derotated misaligned vertebrae either ***one at a time*** ("segmental derotation"), or ***simultaneously*** ("*en bloc* derotation"). (Id. at 88:21-89:12, 156:19-24.)

In the early 2000s, Barry performed multiple *en bloc* derotation surgeries with unlinked levers. (Trial Day 2 Tr. at 21:10-12 (Barry: "So right from December of '02, you know, the multiple cases that I did of [*en bloc*] unlinked levers was important.").) The illustration below depicts an unlinked *en bloc* derotation procedure, showing multiple surgeons simultaneously exerting force on individual levers to manipulate several of the underlying vertebrae in unison.



(PTX223.0007; see also Trial Day 4 Tr. at 103:10-17 ("A. [Barry's expert:] So this is a picture of what's called unlinked derotation. And you can see the number of surgeon hands that are performing that procedure. And so this is what you do if your system didn't have linkages on it. The surgeons would be grasping those reduction tools with their hands and you would actually need more than two surgeons. You can see the fifth hand in that picture.").)

Barry generally preferred *en bloc* to segmental derotation because he believed that "derotating more [vertebral] levels at the same time and spreading those derotational forces amongst a greater number of pedicle screws[] was actually safer." (Trial Day 1 Tr. at 156:15-18.) He endeavored to improve the *en bloc* procedure by ***linking*** levers (or "derotators") longitudinally along multiple vertebral levels to allow derotation of "more levels at the same," while eliminating the "chance [that the] derotator would have moved abnormally with a lot of hands." (Trial Day 1 Tr. at 157:25-158:4, Trial Day 2 Tr. at 95:20-96:7; see also Trial Day 1 Tr. at 137:4-8 ("A [Barry]: Well, it was soon after that that, you know, I realized that if I linked up derotators along the sides that it would take less [sic] hands, it would be—the movement would be much more uniform. It would be safer and potentially more effective.").) He thus invented "a system of derotating vertebrae with linked levers." (Trial Day 1 Tr. at 117: 8-9.)

DePuy manufactures and sells medical instruments allowing surgeons to perform linked *en bloc* derotation (the EXPEDIUM® Vertebral Derotation System and the VIPER® 3D MIS Correction Set). Barry thus accused DePuy of inducing surgeons to infringe his patents. (Am. Compl.); 35 U.S.C. § 271(b). Barry hired a psychologist—David Neal, Ph.D.—to survey the number of infringing procedures surgeons had performed with DePuy instruments.

B. David Neal

Dr. Neal holds a doctorate from the University of Melbourne in psychological and behavioral sciences. He completed a postdoctoral fellowship in psychology and consumer behavior at Duke University, where he was the director of an interdisciplinary social science research laboratory until 2010. (Id. at 45:9-46:15.) Neal founded Catalyst Behavior Sciences, a consulting firm that conducts survey-based work; the chief scientist on a multiyear survey project with the Centers for Disease Control; and a consultant for the United States Army, for which he conducts soldier wellness surveys. (Id. at 46:9-48:2.) He has published twenty-six peer-reviewed papers, nearly all of which involve survey methodology. (Id. at 48:3-23.)

On the third day of trial, I designated Neal as Barry's survey expert. (Trial Day 3 Tr. at 49:21-23; 50:25-51:1; 54:7-9.)

C. The Survey

Neal, Barry's counsel, and Dr. Walid Yassir (Barry's infringement expert) together designed the survey at issue here. (See Trial Day 4 Tr. at 44:17-18 ("A [Neal]: It was done collaboratively. Me, Dr. Yassir, and counsel, correct.").) Neal set out, *inter alia*, to "survey a large representative cross section of surgeons" to determine how many spinal deformity procedures the surgeons performed using DePuy's equipment in a manner that infringed Dr. Barry's patents. (Id. at 54:19-55:3.)

Neal sought to survey spine surgeons, whose email addresses he had collected from three sources: (1) an unquantified list of "orthopedic surgeons, orthopedic spine surgeons, and neurosurgeons" purchased from "IQVIA"; (2) a list of 522 Scoliosis Research Society members that Barry's counsel had provided; and (3) results from a Google search performed by Neal's personal assistant for the terms "orthopedic surgeon scoliosis surgery" and "orthopedic spine surgeon email address"—which yielded 77 more names. (Trial Day 3 Tr. at 67:18-23, 124:5-125:24; Trial Day 4 Tr. at 63:23-25.) Neal could not recall how many emails he sent ("oh, several thousand"), but believed it to be "about 4,000." (Trial Day 3 Tr. at 69:7-18.) Only 164 of the 4,000 (roughly 4%) completed the survey. It thus appears that the IQVIA list provided the great bulk of names. Neal said "IQVIA . . . specializes in finding health professionals to participate in research studies," but offered no evidence as to how its list of surgeons was compiled or for what purpose. (Id. at 67:19-23.) No effort was made to determine anything about the demographics of the 4,000 respondents—*i.e.*, age, gender, geographic distribution, *etc*. Each person who completed the survey would receive a $100 Amazon gift certificate or have a $100 donation made to the Scoliosis Research Society. (Id. at 126:16-20.) Although the survey was supposed to take seven to twelve minutes to complete, the only surgeon who verified this was Barry's infringement expert, Dr. Yassir—who helped design the survey. (Trial Day 4 Tr. at 110:1-6.) As the survey's details were explained, it was apparent that completion should take considerably longer than twelve minutes, especially given the number of surgeries involved. No effort was made to determine if each person responding was, in fact, a surgeon or a support staff member. (Trial Day 3 Tr. at 131:9-10.) Indeed, neither Neal nor anyone else actually spoke to any participant. (Id.)

The first set of survey questions was intended to confirm that participants were physicians or surgeons specializing in general orthopedics, orthopedic spine surgery, pediatric orthopedic surgery, or neurosurgery who: (1) had personally performed spinal deformity procedures between 2016-2018; and (2) could approximate how many such procedures they had performed and how many of those involved pedicle screw and spinal rod implant systems. (Trial Day 3 Tr. at 73:22-24, 74:1-19; see PTX350.)

Participants were next asked to recall in how many of those surgeries they used certain models of instrumentation (such as DePuy's Expedium or Viper tools), and then to approximate the number of surgeries involving "simultaneously rotating 2 or more vertebral bodies in the axial plane." (See PTX350 (Survey Questions 12-14).) Survey participants were thus asked at the outset to consider ***only*** *en bloc* derotation procedures. Once they entered the number of *en bloc* derotation procedures they had performed, they could not later go back and change that entry. (Trial Day 3 Tr. at 135:14-22.) Each participant averaged 80 such procedures over the preceding 2 years—totaling over 13,000 procedures for the 164 respondents. (Id. at 84:6-10.)

Participants were then asked to categorize each of the eighty procedures she had performed. The participants viewed written descriptions and illustrations of six derotation surgery instrument assembly types that Yassir and Barry's counsel had created. Each respondent sorted each reported number of *en bloc* procedures into one those six categories. (Trial Day 4 Tr. at 43:11-21.) For instance, if a participant had first answered that she had performed ten *en bloc* procedures with DePuy instruments, she was required to designate each of those ten procedures as fitting one of those six categories. There was no option to answer, "I don't know," "I don't remember," or "Other." Yet, Neal himself did not know whether the six categories were exhaustive, nor had he

instructed Dr. Yassir or counsel that they *should* be exhaustive. (Trial Day 3 Tr. at 134:22-135:3; Trial Day 4 Tr. at 43:22-44:10, 44:23-45:17.)

Yassir told Neal that five of the six categories described procedures infringing Barry's patents. Neal thus concluded that 6.2% of the approximately thirteen thousand spinal deformity procedures reported by the 164 respondents directly infringed on Barry's patents, with those surgeons using DePuy's equipment. (Trial Day 3 Tr. at 104:22-105:7.)

D. Damages

Upon a finding of infringement, the patentee must prove damages under one of two "alternative categories of infringement compensation": the patentee's lost profits, or the "reasonable royalty he would have received through arms-length bargaining." Lucent Techs., Inc. v. Gateway, Inc., 580 F.3d 1301, 1324 (Fed. Cir. 2009); SmithKline Diagnostics, Inc. v. Helena Lab. Corp., 926 F.2d 1161, 1164 (Fed. Cir. 1991); see 35 U.S.C. § 284. Here, Dr. Barry sought to prove damages based on a reasonable royalty, which "seeks to compensate the patentee . . . for its lost opportunity to obtain a reasonable royalty that the infringer would have been willing to pay if it had been barred from infringing." AstraZeneca AB v. Apotex Corp., 782 F.3d 1324, 1334 (Fed. Cir. 2015); see also Oiness v. Walgreen Co., 88 F,3d 1025, 1030 (Fed. Cir. 1996) ("[D]amages may not be determined by mere speculation or guess." (internal quotations and citation omitted)).

Barry based his damages calculation on Neal's survey data. Damages expert Kimberly Schenk opined that in a hypothetical negotiation, the parties would have agreed to a reasonable royalty rate of $1,200 per infringing procedure. (Trial Day 5 Tr. 85:2-4.) She then extrapolated the survey data (once again, showing that 6.2% of reported spinal deformity procedures infringed Dr. Barry's patents) to the total spinal deformity procedures performed during the 12-year damages period (2011 to 2023) to arrive at a royalty base of 37,893 total infringing procedures. (Id. at

83:16-19.) Applying the royalty rate of $1,200 per infringing procedure to the royalty base of 37,893 infringing procedures, Schenk calculated some $45 million in damages (which Barry would ask me to treble). (Id. at 128:14-17.)

The jury's ability to determine a nonspeculative damages award thus turned entirely on the reliability of Neal's survey and the conclusions he drew from it. (Doc. No. 243 at 7 ("Dr. Neal's survey is the only measure of the amount of DePuy infringing surgeries in this case and . . . Dr. Barry exclusively rel[ies] on Dr. Neal's survey in calculating damages.").)

II. PROCEDURAL BACKGROUND

Well before trial, I denied without prejudice DePuy's Daubert Motion to exclude Neal's survey and expert testimony. (Doc. No. 185 at 1 ("Because I am being asked to make evidentiary trial rulings when trial has not yet begun, my decisions are necessarily tentative. I am prepared to revisit them during trial should any Party ask me to do so.").)

When Barry called Neal at trial, DePuy renewed its Daubert Motion, which I took under advisement, ordering the Parties to submit additional briefing. (Trial Day 3 Tr. at 50:23-51:1, 143:25-144:7.) After considering Neal's testimony and reviewing the submissions, it was apparent that Neal's methodology was flawed and that no reliable conclusions could be drawn from his survey. In re Zoloft (Sertraline Hydrochloride) Prods. Liability Litig., 858 F.3d 787, 792-93 (3d Cir. 2017) (expert evidence must be excluded if methodological "flaw is large enough that the expert lacks the 'good ground' for his or her conclusions" (internal citation omitted)); Walden v. Georgia-Pacific Corp., 126 F.3d 506, 518 n. 10 (3d Cir. 1997) ("Under these and similar circumstances, if a district court makes a tentative pre-trial ruling, it has the opportunity to 'reconsider [its] *in limine* ruling with the benefit of having been witness to the unfolding events at trial.'" (quoting United States v. Graves, 5 F.3d 1546, 1552 (5th Cir. 1993))).

I thus granted DePuy's renewed Daubert Motion on June 26, 2023, noting that I would issue this Memorandum to explain the bases of my ruling more fully. (Doc. No. 252.)

III. LEGAL STANDARDS

In exercising my gatekeeping function, I may admit only reliable scientific or technical testimony and evidence, and must ensure that the expert, "whether basing testimony upon professional studies or personal experience, employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field." Daubert, 509 U.S. at 589; Kumho Tire Co., Ltd. v. Carmichael, 526 U.S. 137, 152 (1999); Fed. R. Evid. 702. To determine whether to admit expert testimony under Rule 702, I evaluate: (1) the expert's qualifications; (2) the reliability of his methodology; and (3) whether the testimony is relevant and helpful for the trier of fact. Fed. R. Evid. 702; Schneider ex rel. Estate of Schneider v. Fried, 320 F.3d 396, 404 (3d Cir. 2003); Breidor v. Sears, Roebuck & Co., 722 F.2d 1134, 1139 (3d Cir. 1983) ("Helpfulness is the touchstone of Rule 702.").

The reliability of Neal's survey methodology was at issue here. An inquiry into reliability ensures that an expert's opinions are based upon "methods and procedures of science rather than on subjective belief or unsupported speculation." In re Paoli R.R. Yard PCB Litig., 35 F.3d 717, 742 (3d Cir. 1994) (internal quotations omitted). The proponent of the expert testimony must show by an evidentiary preponderance that its expert's opinion is reliable. Oddi v. Ford Motor Co., 234 F.3d 136, 144 (3d Cir. 2000). I may assess reliability by considering whether: (1) the theory or technique can be tested; (2) the theory or technique has been peer reviewed; (3) there is a high rate of known or potential error; (4) there are standards of control; (5) the theory is "generally accepted"; (6) there is a sufficient relationship between the technique and methods which have

been established to be reliable; (7) the expert's qualifications are sufficient; and (8) the method has been put to non-judicial uses. Daubert, 509 U.S. at 593-94; Paoli, 35 F.3d at 742 n.8.

The reliability inquiry is "flexible," however, and "the law grants a district court the same broad latitude when it decides *how* to determine reliability as it enjoys in respect to its ultimate reliability determination." Kumho Tire, 526 U.S. 137, 141-42 (1999).

IV. DISCUSSION

Dr. Neal's survey suffers from several defects. His stated goal notwithstanding, Neal failed to interrogate "a large representative cross section of surgeons." (Trial Day 3 Tr. at 54:19-22.) Further, the survey's design flaws ensured that any results would be meaningless. Either of these failings was sufficiently serious to preclude the survey's admission at trial. Added to these were the repeated circularity of Neal's definitions and reasoning, and his failure to perform a pretest, consider non-responsive bias, follow up with those who did respond, or allow respondents to check their surgical records. Considering all these flaws, I ruled that Barry had failed to show by an evidentiary preponderance that the survey and Neal's expert opinion were reliable, and so barred their admission. Cf. Parallel Networks Licensing, LLC v. Microsoft Corp., No. 13-2073, 2017 WL 11557655, at *2 (D. Del. Feb. 22, 2017), aff'd, 777 F. App'x 489 (Fed. Cir. 2019) ("The lack of fit between the survey and the asserted claims is, in and of itself, sufficient to exclude the survey as unreliable and prejudicial under Daubert. Nevertheless, there are additional problems with the survey that warrant discussion and that further support my decision to [exclude].").

A. Preliminary Objections

I first will address Barry's arguments that do not bear directly on the merits of DePuy's renewed Daubert Motion.

In Barry's 2016 suit against another medical device manufacturer, the court admitted a survey Neal had prepared for Barry. Barry v. Medtronic, No. 14-104, 2016 WL 7665773 at *1 (E.D. Tex. July 19, 2016), aff'd 914 F.3d 1310 (Fed. Cir. 2019). I rejected Barry's reliance here on that discretionary ruling. As I explained, the Medtronic litigation involved a ***different*** Neal survey, which, in any event, did not suffer from the same design flaws that I discuss here. (Trial Day 3 Tr. at 75:19-25.)

Barry also asked me to deem as waived Daubert arguments that DePuy raised for the first time in its renewed Motion. Barry had ample opportunity to respond to any new reasoning DePuy offered and so could articulate no prejudice. In these circumstances, I declined to deem that reasoning "waived." Cf. Fraser v. Wyeth, Inc., 992 F. Supp. 2d 68, 97 (D. Conn. 2014) ("Daubert stressed the trial judge's obligation to act as a gatekeeper to ensure that expert testimony is reliable. The insistence on reliability helps to ensure the integrity of the judicial process. That goal is of such obvious and transcendent importance that judges can act *sua sponte* to prohibit testimony that does not pass muster under Daubert.") (internal quotations and citations omitted)).

B. Survey Standards

In the Third Circuit, an admissible survey must comport with the following criteria.

> (1) a proper universe must be examined and a representative sample must be chosen; (2) the persons conducting the survey must be experts; (3) the data must be properly gathered and accurately reported; (4) the sample design, the questionnaires, and the manner of interviewing must meet the standards of objective surveying and statistical techniques; (5) the survey must be conducted independently of the attorneys involved in the litigation; and (6) the sample designers should be trained and, ideally, unaware of the purposes of the survey or the litigation.

Pittsburgh Press Club v. United States, 579 F.2d 751, 758 (3d Cir. 1978). Although a survey's methodological deficiencies generally go to its evidentiary weight rather than to its admissibility, I may nonetheless exclude a survey: (1) under Rule 702 when the deficiencies are so fundamental

that its conclusions are unreliable; or (2) under Rule 403 when the survey is insufficiently probative, unfairly prejudicial, or misleading. Citizens Fin. Grp., Inc. v. Citizens Nat. Bank, 383 F.3d 110, 121 (3d Cir. 2004); Medisim Ltd. v. BestMed LLC, 861 F. Supp. 2d 158, 167 (S.D.N.Y. 2012). Here, Neal's survey fails whether analyzed under Rule 702 or 403.

C. Failure to Establish Sample's Representativeness

Neal's failure to demonstrate representativeness rendered his conclusions unreliable and any resulting damages calculation speculative.

"One of the first steps in designing a survey or in deciding whether an existing survey is relevant is to identify the target population (or universe)." Shari Seidman Diamond, "Reference Guide on Survey Research," in Reference Manual on Scientific Evidence 359, 376 (Fed. Judicial Ctr., 3d ed. 2011). The target population consists of all individuals "whose characteristics . . . the survey is intended to represent." Id.

When a sample is representative of the greater population from which it is drawn, "[d]ata from the sample can be extrapolated to describe the characteristics of th[at] population." David H. Kaye & David A. Freedman, "Reference Guide on Statistics," in Reference Manual on Scientific Evidence 211, 226-27 (Fed. Judicial Ctr., 3d ed. 2011); see id. at 217 ("Inferences from the part to the whole are justified when the sample is representative."). Representativeness is generally satisfied when the researcher "defines an appropriate population, uses a probability method for selecting the sample, has a high response rate, and gathers accurate information on the sample units." Id. at 226. "Of course, surveys may be useful even if they fail to meet these criteria. But then, additional arguments are needed to justify the inferences." Id. at 227.

Unfortunately, the target population of Neal's survey was a moving target. He first testified that the "universe of [his] survey" was "spine surgeons who are performing [specifically] pedicle

screw surgeries involving simultaneous derotation." (Compare, e.g., Trial Day 3 Tr. at 57:20-25, with id. at 62:1-5.) In opposing DePuy's Renewed Daubert Motion, however, Barry argued that there was "no doubt" that the target population was "surgeons who perform spinal deformity surgeries in the United States." (Doc. No. 243 at 14.)

Neal insisted that it was "literally impossible" to describe quantitatively his survey's universe, however Barry chose to define that universe. (See, e.g., Trial Day 3 Tr. at 118:7-16.) He dismissed as "useless" the suggestion to "determine if there w[as] a list of surgeons who were licensed to practice medicine in the United States." (Id. at 121:25-122:8.) Eventually, he reluctantly estimated that there were some 50,000 spinal surgeons in the United States. (Id. at 56:11-16.)

The reliability issues arising from Neal's failure to identify consistently or quantify his universe of surgeons were compounded by the way he chose his survey recipients. He did not use a probability method for selecting the sample, nor did he conduct the survey "independently of the attorneys involved in th[is] litigation." Pittsburgh Press Club, 579 F.2d at 758. Compare Shari Seidman Diamond, "Reference Guide on Survey Research," in Reference Manual on Scientific Evidence 359, 380 (Fed. Judicial Ctr., 3d ed. 2011) ("The use of probability sampling techniques maximizes both the representativeness of the survey results and the ability to assess the accuracy of estimates obtained from the survey. . . . In . . . probability sampling, every element in the population has a known, equal probability of being included in the sample, and all possible samples of a given size are equally likely to be selected."), with id. at 419 (a nonprobability convenience sample is a "sample of elements selected because they were readily available"). The great bulk of survey recipients were provided by IQVIA, which purportedly "specializes in finding health professionals." (Trial Day 3 Tr. at 67:19-23.) Once again, Neal offered no evidence as to how

IQVIA's list of surgeons was compiled or for what purpose. Neal never spoke with any of the 164 respondents. Surgeons in 13 states were unrepresented. (Doc. No. 235-1 at 15.) Twelve states had only one respondent each. (Id.)

As I have discussed, to obtain the "large representative cross section" of the target population he sought, Neal drew on three sources: (1) results from a Google search by Neal's "personal assistant," using "the terms orthopedic surgeons, scoliosis surgery, and orthopedic spine surgeon email addresses"; (2) a list of Scoliosis Research Society members that Barry's counsel had provided; and (3) a list of "orthopedic surgeons, orthopedic spine surgeons, and neurosurgeons" that Neal had purchased from IQVIA. (Id. at 54:19-22, 67:18-23, 122:22-25, 124:5-125:24; Trial Day 4 Tr. at 63:23-25.) Neal sent over 4,000 emails to this group, asking them to complete the survey and either receive a $100 Amazon gift card or have a $100 donation made to the Scoliosis Research Society. (Trial Day 3 Tr. at 126:17-21.) Neal did not indicate how many respondents took the gift card and how many took the donation.

In one of his many *ipse dixit* conclusions, Neal testified that the self-selected 164 people who completed the survey was a "representative" sample:

> Q. The only support that we have for your statement that this is a representative sample is the fact that you said it, correct?
> A. [Neal:] That's correct.

(Id. at 119:17-20.) Once again, Neal made no effort to contact any respondent after the survey. (Id. at 130:24-131:10.) When asked how he could know if each respondent was in fact a spinal deformity surgeon—and not her "personal assistant"—Neal said, "I have never seen that happen." (Id. at 128:7-21.) He made no effort to ensure all states were represented in his sample, or to provide a demographic breakdown by experience or gender. (Id. at 120:1-23.) Rather, only after the fact, Barry's lawyers asked Neal to "guess" the age of each respondent based on when she had

graduated from medical school. (Id.) Neal did not "compare that age distribution to any large population of surgeons in the U.S." (Id. at 121:16-21.) When asked how he determined that the survey questions were "unbiased," Neal offered yet another circular response: "unbiased is established by looking at the evenhandedness of the questions." (Id. at 60:4-6.) Nor did Neal address non-response bias, even though the response rate to his 4,000 invitations was only 4.1%. (Id. at 127:12-18.)

Given that representativeness was thus suspect, it would have been important for Neal to determine if non-response bias tainted his survey. Marlo v. United Parcel Service, Inc., 251 F.R.D. 476, 485 (C.D. Cal. 2008) (excluding survey where proponent failed to "take measures to assure that nonresponses are random and provide analysis of the reasons of nonresponse"); Sec. Alarm Fin. Enter., L.P. v. Alder Holdings, LLC, No. 13-102, 2017 WL 5248181, at *4 (D. Alaska Feb. 21, 2017) ("[T]he Court is particularly concerned because [the expert] does not address nonresponse bias—indeed, the report itself does not even disclose how many individuals failed to respond to the survey."); In re: Autozone, Inc., 2016 WL 4208200 at *17 (excluding survey with 6% response rate); In re ConAgra Foods, Inc., 90 F. Supp. 3d 919, 951 (C.D. Cal. 2015) (excluding survey when, among other deficiencies, it had a 5% response rate); Wallace v. Countrywide Home Loans Inc., No. SACV 08-1463-JST (MLGx), 2012 WL 11896333, at *4 (C.D. Cal. Aug. 31, 2012) (excluding survey under Daubert: "A survey that 'begins with a random sample,' but does not 'take measures to assure that the nonresponses are random and provide analysis of the reasons of nonresponse' is not 'the product of reliable principles and methods.'"). Neal failed to make such a determination because he felt that non-response bias is "not a major contributor to the quality of survey results." (Trial Day 3 Tr. at 127:15-18.)

The representativeness issue was further compounded by Neal's failure to conduct a follow-up with any of the survey's respondents. Given their small number—164 people—follow-up would not have been burdensome, and would have given Neal the opportunity to allay a number of the concerns I have discussed, as would pretesting. Cf. Malletier v. Dooney & Bourke, Inc., 525 F. Supp. 2d 558, 575 (S.D.N.Y. 2007) (failure to utilize follow-up questions to prompt respondents to explain their answers was a flaw that "quelled" any doubt about a study's exclusion); BBK Tobacco & Foods LLP v. Central Coast Agriculture Inc., 615 F. Supp. 3d 982, 1004-05 (D. Ariz. 2022) (follow-up questions, intended to assess respondents' confidence and ensure that their responses were more than mere guesswork, enhance survey reliability); Capri Sun GmbH v. Am. Beverage Corp., 595 F. Supp. 3d 83, 127 (S.D.N.Y. 2022) ("[A] pretest may enhance the court's confidence in a survey's reliability."); Blumenfeld Dev. Corp. v. Carnival Cruise Lines, Inc., 669 F. Supp. 1297, 1315 (E.D. Pa. 1987) ("There were numerous technical errors in the survey which damage its reliability and validity including . . . the absence of a pretest . . . ."). Once again, Neal failed to take these steps. He suggested that the survey he conducted in Medtronic years before could serve as a pretest, but that survey—with different respondents and different questions—could hardly serve as an actual pretest. (Trial Day 3 Tr. at 64:1-25.) His other suggestion—that Yassir's review of the "final version" of the *questions he wrote* "to make sure that it made sense" was a "form of pretesting"—is simply incorrect. (Id.); see Deere & Co. v. Farmhand, Inc., 560 F. Supp. 85, 93 n.13 (S.D. Iowa 1982) ("The process of pretesting is a survey technique designed to determine whether the panel members understand the question presented to them."). He also offered no reason for his refusal to conduct any follow up. (Id. at 130:15-16 ("I made no check to do that.").) Not surprisingly, Neal failed to show, except by his

own *ipse dixit* conclusions, that the survey comported with accepted "quality controls and . . . scientific rigor." (Id. at 113:15-18.)

In these circumstances, I determined that Barry had failed to show reliability by an evidentiary preponderance and so excluded Neal's survey and the testimony based on that survey. See Pittsburgh Press Club, 579 F.2d at 759 (excluding survey because the sample "was not designed to be representative"); Parallel Networks Licensing, 2017 WL 11557655, at *4-5 ("The problem is that [the expert] does not consider whether the survey respondents reflected a representative sample of the desired population."); Hostetler v. Johnson Controls, Inc., No. 15-226, 2017 WL 3700345, at *2 (N.D. Ind. Aug. 28, 2017) (striking survey evidence because expert "never considered whether the individuals they succeeded in identifying were representative of the class as a whole"); In re Autozone, Inc., Wage and Hour Employment Practices Litig., No. 10-md-2159, 2016 WL 4208200, at *17 (N.D. Cal. Aug. 10, 2016) (excluding survey because expert "offers no explanation of why the 343 responding class members adequately stand in for the class as a whole, simply because each worked at least one of the relevant shifts"), aff'd, 789 F. App'x 9 (9th Cir. 2019); Marlo, 251 F.R.D. at 485 (excluding survey evidence after the proponent of that evidence admitted that she did not know whether the survey sample was representative and did not do anything to evaluate whether the sample was representative), aff'd, 639 F.3d 942 (9th Cir. 2011).

D. Flawed Question Design

The survey's serious design flaws rendered its results meaningless and, again, unreliable.

Type 1 Category Definitional Problem

As I have discussed, the survey required surgeons to report a threshold number of surgeries involving "simultaneously rotating 2 or more vertebral bodies in the axial plane." (See PTX350

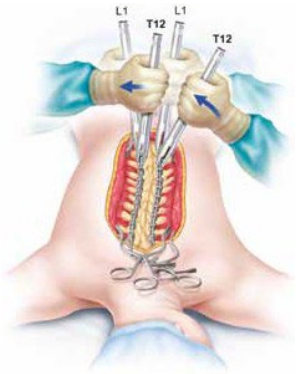
(survey question 14).) Survey participants were thus asked to consider and report ***only*** the total number of *en bloc* derotation procedures. Once locked into that number of reported *en bloc* derotation procedures, the survey participants were asked to study the six surgery assembly types Neal and Yassir had created before allocating their *en bloc* derotation procedures.

Yet, one of the assembly categories, Type 1, did not describe *en bloc* derotation at all. Rather, Type 1 described segmental derotation (once again, a procedure involving derotation of ***one vertebra at a time***), showing assembly variations using only unlinked derotators or derotators linked across the same vertebra. (PTX 350 (Neal Survey, Type 1).) Accordingly, a survey participant asked to categorize her *en bloc* procedures accurately would necessarily report ***zero*** Type 1 surgeries. Neal testified, however, that "the most frequently reported type of surgery was actually [Type] one," with nearly half of the survey participants reporting Type 1 surgeries. (Trial Day 3 Tr. at 104:3-7; Doc No. 235-1, Ex. B, Neal Report at 37, Table 15.) This made no sense.

Responding to this apparently fatal design flaw, Barry sought to argue that DePuy's proffered definition of segmental derotation ("rotating multiple vertebral bodies one at a time") was incorrect, urging that segmental derotation referred only "to the movement of an individual segment of the vertebrae ***unlinked*** to any other vertebrae" and thus qualified as a surgery involving "simultaneously rotating 2 or more vertebral bodies in the axial plane." (Doc No. 235-1 at 20; Doc. No. 243 at 28 (emphasis added).) Barry thus suggested that when surgeons manipulate multiple segments of vertebrae ***simultaneously***, they are performing a segmental derotation, so long as those segments are unlinked to other vertebrae. Yet, the trial evidence presented by Barry—including his own testimony—uniformly refutes this contention.

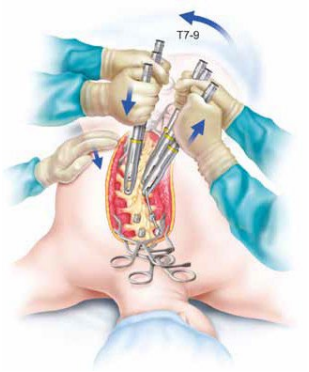
The DePuy Expedium Manual (an FDA required document authored by surgeons) is among the materials Barry alleged had induced spinal surgeons to directly infringe his patents.

Yet, the Manual explicitly describes segmental derotation as derotation of individual vertebrae ***one at a time***—a technique distinct from *en bloc* derotation, which involves ***simultaneous*** derotation of multiple vertebrae, regardless of whether the levers are unlinked or linked along multiple vertebrae. (Trial Day 4 Tr. at 23:8-10, 157:20-21.) For instance, the "Segmental Vertebral Body Derotation (Individual Vertebral Level)" instruction directs the surgeon to attach a pair of levers for manipulation of an individual vertebra (T12 in the figure below) and a pair of levers to the next proximal vertebra (L1 in the figure below) to be "held by an assistant to provide counter-rotation force," and then instructs the surgeon to derotate the vertebra, tighten the screws, and repeat the process for each vertebra requiring derotation, ***one at a time***.



(PTX223.0010, Figure 11A.)

The Manual also includes two diagrams (with accompanying instructions) for "En Bloc Vertebral Body Derotation (Multiple Apical Levels)." The first instructs surgeons on unlinked *en bloc* derotation: two sets of hands are shown rotating two vertebral levels ***simultaneously*** by applying force to unlinked levers, while a fifth hand presses down on the ribs (below on the left). The second shows that individual levers "can be linked together and rotated in unison" for linked *en bloc* derotation (below on the right).



(PTX 223.0007, 223.0008, Figures 6 and 8.) Plainly, segmental derotation is distinct from unlinked *en bloc* derotation.

Barry's suggestion that segmental derotation somehow referred to unlinked *en bloc* derotation thus contradicts not only the Manual but his ***own*** use of those terms as well. Barry testified that segmental derotation is distinct from procedures allowing derotation of multiple vertebrae at the same time:

> But, you know, the derotation was done, you know, in the past. ***Segmental, one level, two levels***. But, again, ***adding levels*** made it safer by distributing the forces and other safety things, too. You know, the efficiency of derotating ***everything at once*** dramatically cut down the length of surgeries.

(Trial Day 1 Tr. at 156:24-157:3; see also Doc. No 104-3 ¶ 128 ("Barry states as follows . . . surgeons had derotated individual vertebra one at a time – known as segmental derotation.").) Barry himself called simultaneous derotation of multiple vertebrae with levers unlinked to other vertebrae—the very procedure he now claims is encompassed by the term "segmental derotation"—unlinked *en bloc* derotation. (Trial Day 1 Tr. at 149:21-23, 152:22-23 ("Basically I was building on my existing technique of unlinked unblocked [*sic*] derotation.").) Dr. Yassir, who, once again, helped create the six survey categories, testified similarly:

> Q. [Plaintiff's counsel:] Is what we see in Figure 6 with the five hands, is that use of a DePuy instrument set infringing on Dr. Barry's patents?
> A. [Yassir:] No, it's not.
> Q. Why not?

> A. Because the derotators are not linked to each other, so this does not infringe Dr. Barry's patent.
> Q. Does this resemble the unlinked *en bloc* derotation that we've heard discussed this week?
> A. Yes.

(Trial Day 4 Tr. at 104:1-10.)

It was thus uncontroverted at trial that segmental derotation referred only to procedures by which vertebrae are manipulated ***one at a time***. Accordingly, survey participants asked to report the number of *en bloc* derotation procedures (*i.e.*, those procedures involving "simultaneously rotating 2 or more vertebral bodies in the axial plane") could not accurately categorize *any* of those procedures as Type 1 segmental derotation. That nearly half of the respondents nonetheless reported Type 1 procedures thus strongly suggests that they provided senseless responses in their 7 to 12 minute completion of a survey calling upon them to recall the details of some 80 surgeries each had performed over the previous 2 years. At the very least, this muddled result severely undermined the survey's reliability. Cf. J&J Snack Foods, Corp. v. Earthgrains Co., 220 F. Supp. 2d 358, 370 (D.N.J. 2002) ("Because the classifications were not properly-defined, the survey has no bearing on the issue it was submitted for.").

Closed-Ended Categorization with Non-Exhaustive Categories

Finally, the survey failed to include a category for unlinked *en bloc* derotation procedures, which Yassir concedes do not infringe Barry's patents. (Trial Day 4 Tr. at 104:6-7.) Rather, the remaining categories—Types 2 through 6—showed variations only of ***linked*** *en bloc* derotation procedures, all of which Yassir had determined infringed the patents. (See PTX350 (Neal survey); Trial Day 4 Tr. at 106:8-107:1.)

Because participants were not given the option to answer, "I don't know," "I don't remember," or "Other," the survey, by its design, compelled erroneous reporting: surgeons that

performed non-infringing unlinked *en bloc* derotation procedures could either categorize these procedures ***inaccurately*** as segmental derotation procedures (Type 1) or ***inaccurately*** as one of the five allegedly infringing linked *en bloc* derotation procedures (Types 2-6). (See PTX350; Trial Day 3 Tr. at 134:22-135:3; Trial Day 4 Tr. at 43:22-44:10.) This structural defect stripped the survey responses of any probative value. See Shari Seidman Diamond, "Reference Guide on Survey Research," in Reference Manual on Scientific Evidence 359, 389 (Fed. Judicial Ctr., 3d ed. 2011) ("If the respondent is asked to choose one response from among several choices, the response chosen will be meaningful ***only if the list of choices is exhaustive***." (emphasis added)). For this reason as well, I determined that Barry had failed to show the survey's reliability by an evidentiary preponderance, and so barred its admission.

C. CONCLUSION

As I have discussed, flaws in an expert's methodology usually go to the weight, not the admissibility of the expert's evidence. Here, however, there was no showing of reliability. Dr. Neal's methodology was so flawed that any damages calculation based on that methodology was necessarily speculative. Moreover, because the survey was flawed and muddled, its admission would certainly have confused and misled the jury. Cf. Wing Enters., Inc. v. Tricam Indus., Inc., 829 F. App'x 508, 515-16 (Fed. Cir. 2020) (district court did not abuse its discretion in excluding testimony about a survey due to jury confusion). In these circumstances, I barred Neal's survey and testimony.

BY THE COURT:

/s/ Paul S. Diamond

Paul S. Diamond, J.